

User Manual

Models 314A-G

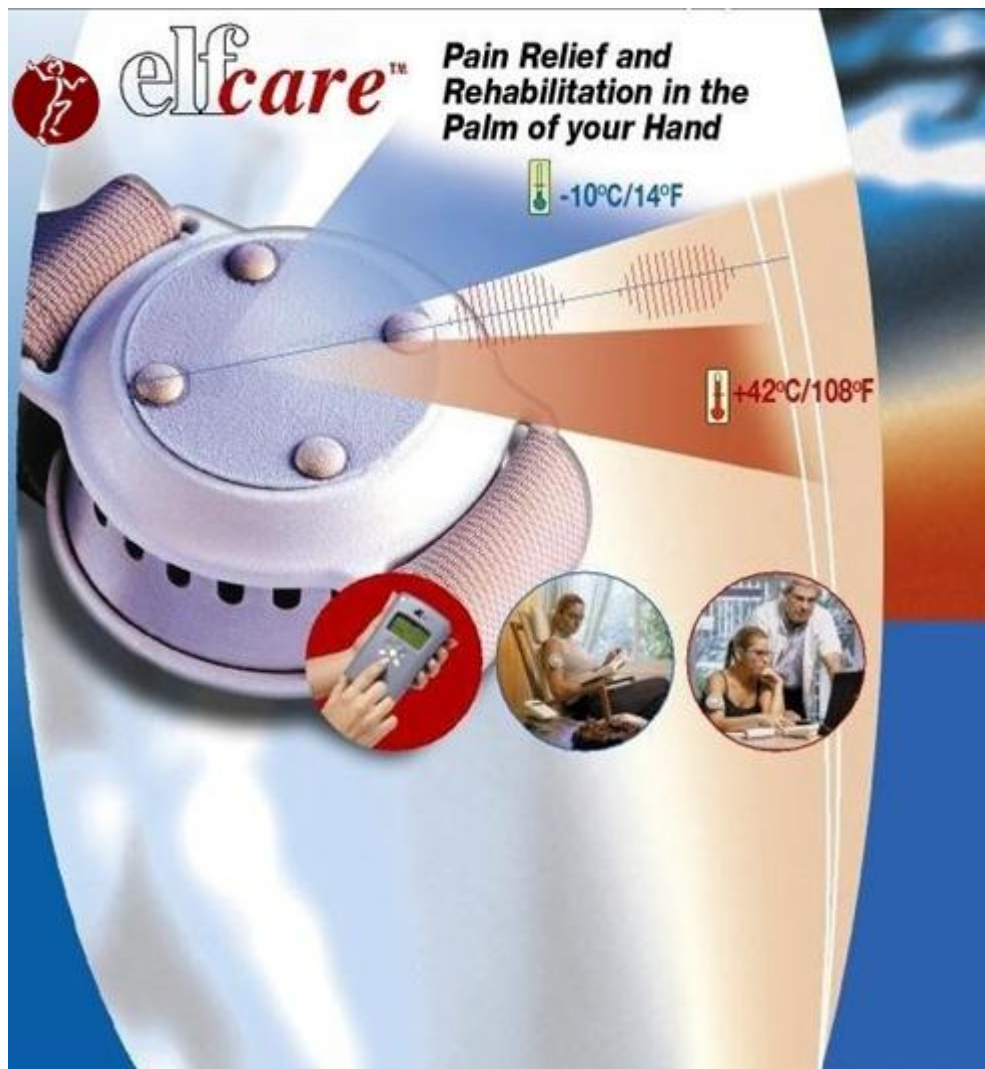


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PRODUCT DESCRIPTION

The **ELFcare™** device is a unit that has the ability to combine hot or cold therapy and electrotherapy to provide high quality performance in pain management and rehabilitation. The **ELFcare™** device makes use of an electronically controlled ThermoElectrode that can be operated in cooling or heating modes. The ThermoElectrode is connected and controlled by the Control Unit.

Thermotherapy:

The **ELFcare™** device produces accurately controlled cold, hot and cycling cold/hot therapy.

Electrotherapy:

The **ELFcare™** device produces Electrotherapy using ThermoElectrode and Ordinary electrodes. The **ELFcare™** offers up to 100 treatment protocols.

ELFcare™ is a prescription device used under the supervision of or by order of a physician or other licensed healthcare provider.

The **ELFcare™ device has been designed in accordance with appropriate safety standards and includes numerous protective circuits to assure safe operation.**



IMPORTANT SAFETY INSTRUCTIONS

BEFORE USING THE **ELFcare™ UNIT, BASIC SAFETY PRECAUTIONS SHOULD ALWAYS BE FOLLOWED TO REDUCE THE RISK OF FIRE, ELECTRICAL SHOCK AND INJURY TO PERSONS, INCLUDING THE FOLLOWING:**

1. No attempt should be made to disassemble the unit. Maintenance and all repairs should be made by authorized personnel only. The manufacturer will not be held responsible for the results of maintenance or repairs by unauthorized persons.
2. The ThermoElectrode should be used only after a layer of conductive gel has been applied to ThermoElectrode built in electrodes or after assembly to ThermoElectrode reusable Pad and putting conductive gel to electrode areas of Pad.
3. Ordinary Reusable electrodes should be used only after a layer of conductive gel has been applied to electrodes.
4. Some patients may experience skin irritation or hypersensitivity due to electrical stimulation or electrical conductive medium. The irritation can usually be reduced by using an alternative conductive medium, or alternate electrode placement.
5. Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner.

The instructions given below should be followed by the user in order to ensure proper operation of this unit:

1. Follow all warnings and instructions marked in this user manual and on the **ELFcare™** device.
2. Unplug the **ELFcare™** device from the power outlet before cleaning. Do not use liquid cleaners or aerosol cleaners. Use damp cloth for cleaning.
3. Do not use the **ELFcare™** device near water and never spill liquid of any kind on the device.
4. Slots or openings in the ThermoElectrode are provided for ventilation, to protect it from overheating. These openings must not be blocked.
5. **ELFcare™** device should be used only with the leads wire and electrodes recommended for use by the manufacturer.
6. When using the external power source, make sure to use only the Power Supply provided with the **ELFcare™** device. Using another Power Supply is unsafe and may also damage the unit.
7. When the device is connected via USB cable to a personal computer, the electrodes must not be applied to the patient's skin and must be disconnected from the Control Unit.
8. Never push objects of any kind into the **ELFcare™** device slots as they may touch dangerous voltage points or short out parts. This could result in the risk of fire or electric shock.
9. Unplug the **ELFcare™** device and send for servicing to a qualified service technician under the following conditions:
 - a. When any cord or plug is frayed or damaged.
 - b. If liquid has been spilled onto the device.
 - c. If the device has been exposed to water.
 - d. If the product does not operate normally when following the operating instructions.
 - e. If the device has been dropped and has been damaged.
 - f. If the device exhibits a distinct change in performance.
 - g. When the internal batteries cannot be charged.



WARNINGS AND PRECAUTIONS

Federal Law (USA) restricts this device to sale by or on the order of a physician.

1. The safety of **ELFcare™** for use during pregnancy or childbirth has not been established.
2. The **ELFcare™** is not effective for pain of central origin (this includes headaches).
3. The **ELFcare™** should be used only under the continued supervision of a physician.
4. The **ELFcare™** has no curative value.
5. The **ELFcare™** is a symptomatic treatment that suppresses pain sensation that would otherwise act as a protective mechanism.
6. Stimulation should not be applied over, or in proximity to, cancerous lesions.
7. Whilst the **ELFcare™** is in use, electronic monitoring equipment (such as ECG monitors and ECG alarms) may not operate properly.
8. Keep this device out of the reach of children.
9. Isolated cases of skin irritation may occur at the site of electrode placement following long-term application.
10. The **ELFcare™** device should not be used while driving, operating machinery, or during any activity in which involuntary muscle contractions may put the user at undue risk of injury.
11. Effectiveness is highly dependent upon patient selection by a person qualified in the management of pain patients.
12. Precautions should be taken in the following cases:
 - I. Following recent surgical procedures especially when muscle contractions could disrupt the healing process
 - II Where sensory nerve damage is evidenced from loss of normal skin sensation
 - III. Where there is a tendency to hemorrhage following acute trauma or fracture
 - IV. Over the menstruating uterus
13. Current density may exceed 2 mA r.m.s./cm²
14. The **ELFcare™** is not suitable for use in the presence of flammable mixtures
15. The Thermoelectrode may reach a minimum temperature of 5°C on the skin surface.

CONTRAINDICATIONS

1. Do not place electrodes on the carotid sinus (neck) region.
2. Do not use this device if you have an implanted electronic device (e.g. a pacemaker).
3. Do not place electrodes on the head (transcerebrally).
4. Application of electrodes near the thorax may increase the risk of cardiac fibrillation.
5. Do not use for undiagnosed pain until etiology is established.
6. Adequate precautions should be taken when treating individuals with suspected or diagnosed heart problems.
7. Adequate precautions should be taken in the cases of persons with suspected or diagnosed epilepsy.
8. Severe spasm of the laryngeal and pharyngeal muscles may occur if the electrodes are placed over the neck or mouth. The contractions may be strong enough to cause breathing difficulty or even close the airway.
9. Therapeutic electrical stimulation should not be applied over swollen, infected or inflamed areas of skin eruptions (e.g. phlebitis, thrombophlebitis and varicose veins).
10. Use extreme caution in transthoracic application of therapeutic electrical stimulation; introduction of electrical current into the heart may cause arrhythmia.
11. Do not use this device simultaneously with high frequency surgical equipment or stimulators.
12. Do not use this device in close proximity to short-wave or microwave therapy equipment

ADVERSE REACTIONS

Potential adverse reactions include skin irritation and electrode burns.

ELFCARE COMPONENT

Control Unit

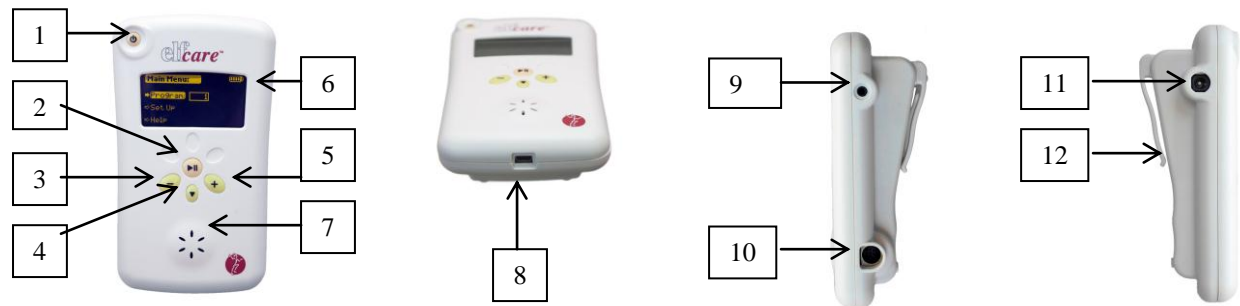


Figure 1: Control Unit

1. **On/Off** Switch
2. **Start/Pause** Switch
3. (-) Switch
4. (↓) Switch
5. (+) Switch
6. Display
7. Speaker
8. USB connector
9. Socket for Ordinary Electrodes Lead Wire
10. ThermoElectrode Socket
11. External Power Input
12. Belt Clip

ThermoElectrode

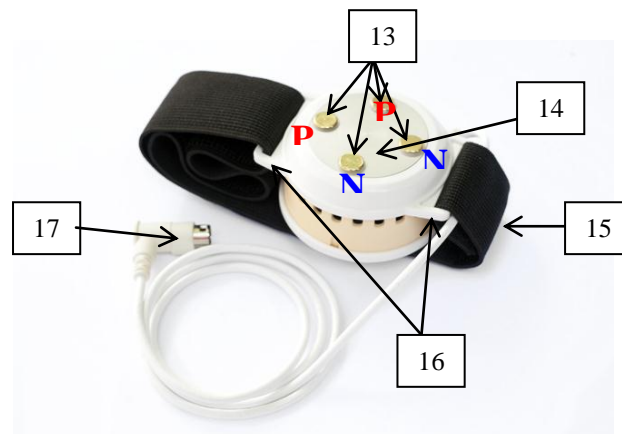


Figure 2: ThermoElectrode

13. Electrodes (**N** / **P** – negative/positive)
14. Thermal Surface
15. Belt
16. Belt Holders
17. ThermoElectrode Plug

Lead Wire

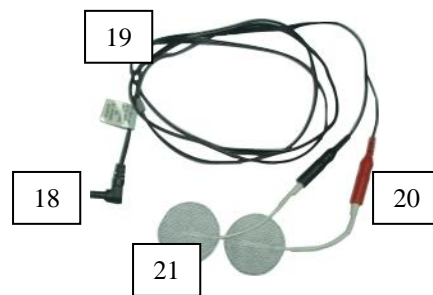


Figure 3: Lead Wire and Ordinary electrodes

- 18. Plug for Control Unit connection
- 19. Lead Wires
- 20. Red & Black “banana” plugs
- 21. Ordinary electrodes

Power Supply

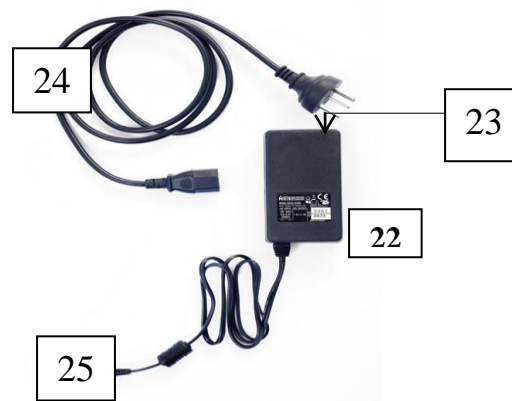


Figure 4: Power Supply

- 22. AC/DC Power Supply
- 23. AC Input
- 24. Cable
- 25. DC Output plug

SYSTEM SETUP

Device Powering

The **ELFcare™** may be powered from its built-in battery or from the supplied external Power Supply.

Battery

The **ELFcare™** unit includes a built-in rechargeable battery.

The operation span of the device when the battery is fully charged is between 1 to 5 hours, depending on program and power consumption.

External Power Supply

The purpose of the external Power Supply (שגיאה! מקור ההפניה לא נמצא.) is to power the Control Unit in longer treatment usage and to provide charge for the internal battery. The external Power Supply can also enable.

The external Power Supply is a Medical Grade AC/DC converter with wide range input voltage.



The Battery must be charged using the External Power Supply provided with the device only.

Charging the Battery

Connect the AC/DC Power Supply (22) DC Output plug (25) into the External Power Input (11) on the Control Unit and then plug the Power Supply into the AC power outlet via cable (24). You will get Charging screen if Control Unit connected with Power Supply.



INSTALLATION

Setup with ThermoElectrode

1. Assembly Pad with ThermoElectrode.
2. Insert ThermoElectrode Plug (17) into the Control Unit ThermoElectrode Socket (10).



Figure 5: Setup with ThermoElectrode

Setup with Ordinary Electrodes

- Insert the Lead Wire Plug (18) into Control Unit socket (9).
- Connect Red and Black “Banana” plugs (20) into Ordinary electrodes (21) leads.

Setup with ThermoElectrode and Ordinary Electrodes

- Insert ThermoElectrode Plug (17) into the Control Unit ThermoElectrode Socket (10)
- Assembly Pad with ThermoElectrode
- Insert the Lead Wire Plug (18) into Control Unit socket (9).
- Connect Red and Black “Banana” plugs (20) into Ordinary electrodes (21) leads.



Figure 6: Setup with Ordinary Electrodes



Figure 7: Setup with ThermoElectrode and Ordinary Electrodes

PREPARATION TO TREATMENT

Use the following guidelines:

- Examine the skin for any wounds and clean the skin.
- Liberally apply Conductive Gel to Pad electrodes area.
- Apply ThermoElectrode to the treatment area.
- Ensure the electrodes (13) are in contact with patient skin (sample in Figure 8).
- Remove the Ordinary electrodes from the protective backing.
- Apply the electrodes to the treatment area (sample in Figure 8).
- Ensure the electrodes are applied securely to the skin.
- Ensure good contact between each electrode and the skin.
- Check the electrode contact regularly during the treatment.
- Keep electrodes separated during treatment. Electrodes in contact with each other could result in improper stimulation or skin burns.
- Examine the skin again after the treatment



Figure 8: Installation Samples

Conductive Medium

Liberal apply Conductive Gel to electrodes of ThermoElectrode prior to placement on patient.



Figure 9: Applying conductive gel on electrodes

Assembly with disposable Pad



Figure 10: Assembly with Disposable Pad

After assembly of disposable pad with ThermoElectrode liberal apply Conductive Gel to disposable pad electrodes area prior to placement on patient.

In case of ThermoElectrode use without a disposable protective pad, it is necessary to disinfect the surfaces of a ThermoElectrode contacting the skin of the patient with spirit solution.

OPERATION

Active Switches

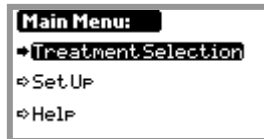
The **ELFcare™** Control Unit includes active switches and voice and visual messages, making operation easy, user-friendly and efficient.

Control Unit is operated using 5 active switches :

| Button number: | Function: | Description: |
|----------------|-------------|---|
| 1 | On/Off | It is used for <i>On/off</i> function |
| 2 | Start/Pause | It is used for selection of options or protocols. |
| 3 | (-) | Located on the bottom left of the button pad. It has several uses: a. (-) is used to exit from each screen in order to return to the previous screen b. (-) is used to lower temperature or current if necessary during treatment (enabled within safety limitations) c. (-) is used for adjusting numbers wherever required (Clock Set, Advanced Mode Password etc.) |
| 5 | (+) | Located on the bottom right of the button pad. It has several uses: a. (+) is used to raise temperature or current if necessary during treatment (enabled within safety limitations) b. (+) is used for adjusting numbers wherever required (Clock Set, Advanced Mode Password etc.) c. (+) is used for getting more information about an option (e.g. in Advanced Mode) |
| 4 | (↓) | Located on the bottom center of the button pad. It is used for scrolling down through options, Treatment no. and information. |

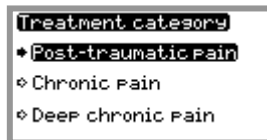
QUICK START

Press “On/off” button



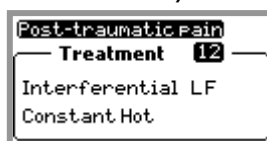
“(↓)” button for scrolling menu

Press “Start/Pause” button for Treatments Category Menu



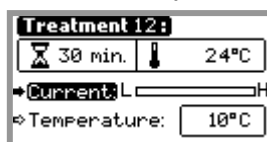
(↓) button for scrolling between treatments category
(-) button for return to Main Menu

Press “Start/Pause” for choose Treatment



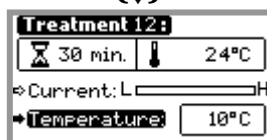
(+) button for information about treatment
(↓) button for scrolling between treatments
(-) button for return to Treatments Category Menu

Press “Start/Pause” button for Treatment Start



(+/-) buttons to adjust Current intensity

Press “(↓)” button



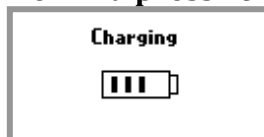
(+/-) buttons to adjust Target Temperature

For Treatment Pause press “Start/Pause” button



For return to Treatment press “Start/Pause” button;
For return to Treatment Selection and
the End of current Treatment press (-) button
For Treatment description press (+)

For End press “On/off” button



You will get Charging screen if Control Unit connected with Power Supply

OPERATIONAL MENUS

Start-Up Menu

The Start-Up Menu will appear for only 3 seconds after turning on the unit.



Figure 11: Start-Up Menu screen

Main Menu

The Main Menu includes three functions:

- Treatment Selection
- Set Up
- Help

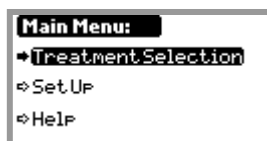


Figure 12: Main Menu screen

Press the “Start/Pause” button to accept the Treatment Selection.

Use the (↓) button to scroll down between Treatment Selection, Setup or Help.

Treatment Category

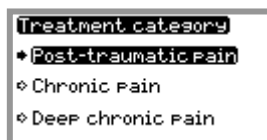


Figure 13: Treatment Category screen

Use the (↓) button to scroll down between Treatments categories

Treatment Selection

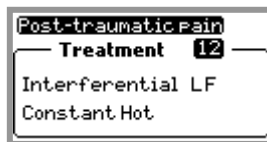


Figure 14: Treatment Selection screen

Press the (↓) button for scrolling.

The unit will display the following information:

1. Kind of Electrical Treatment
2. Kind of Thermo Treatment

TREATMENT

The treatment starts immediately after selecting the desired program. The unit will display the following information:

1. Remaining duration of treatment (in minutes);
2. Electrode surface temperature (ThermoElectrode connected);
3. Current intensity range;
4. Target temperature (ThermoElectrode connected);

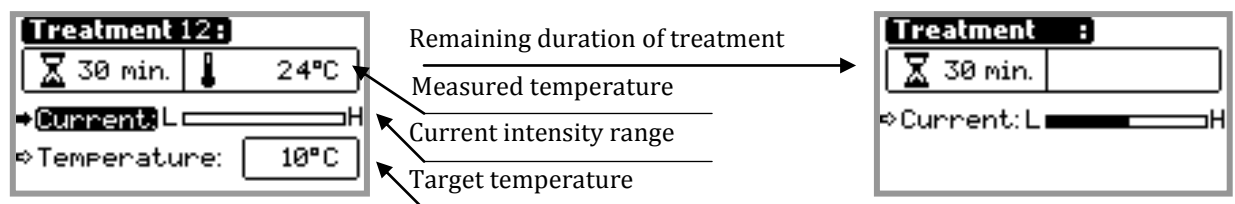


Figure 15: Treatment screens with / without ThermoElectrode

Changing the Current / Temperature

1. Press (+) or (-) to increase or decrease the current intensity/target temperature.
2. Use the (↓) button to scroll between 'Current' and 'Temperature' scales.

Pausing the treatment

Pressing the "Start/Pause" button will stop the treatment immediately and the 'Pause' screen will appear.

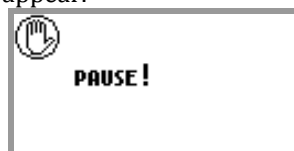


Figure 16: Pause screen

1. While in pause mode the electrode temperature will remain stabilized, and the electrical stimulation will be stopped. The indicator showing the remaining treatment duration will be paused.
2. Pressing the "Start/Pause" button again will restart the program from the point where it was paused.
3. Pressing the (-) button will terminate the treatment program.

End of treatment

1. When the selected treatment program has ended, the **ELFcare™** unit will be switched off automatically.
2. If using the External Power Supply, first remove it from the AC power outlet and then disconnect the Power Supply lead (25) (Figure 4) from the External Power Input (11) (Figure1) on the **ELFcare™** control unit.

SETUP

The parameters for Volume, Display Contrast are set or changed through the Setup mode. In addition, Advanced Mode settings are accessed through the Setup mode.

Setting the Sound Volume

In the Setup Menu:

1. Press the (↓) button to scroll down to 'Volume'.
2. Press the **"Start/Pause"** button while 'Volume' is highlighted. A level bar will be presented beside it.
3. Adjust the volume using the (+) and (-) buttons.
4. Press the **"Start/Pause"** button to accept the changes.

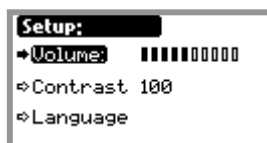


Figure 17: Display Volume screen

Setting the Display Contrast

In the Setup Menu:

1. Press the (↓) button to scroll down to 'Contrast'.
2. Press the **"Start/Pause"** button while 'Contrast' is highlighted. A level bar will be presented beside it.
3. Adjust the display contrast using the (+) and (-) buttons.
4. Press the **"Start/Pause"** button to accept the changes

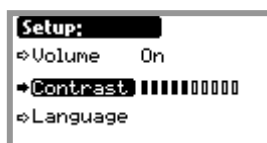


Figure 18: Display Contrast screen

Setting the Language

In the Setup Menu:

1. Press the (↓) button to scroll down to 'Language'.
2. Press **"Start/Pause"** button for select Menu Language.
3. Use the (↓) button to scroll down between languages.
4. Press the **"Start/Pause"** button to accept the changes.



Figure 19: Display Language screen

ADVANCED MODE

This mode is for professional use only. In order to gain access to the protocol library and enable protocols for treatment, a four-digit password must be entered.

In the Setup Menu:

1. Press the (↓) button until the Advanced Mode option is highlighted, and select it using the “Start/Pause” button.
2. Click the (+) or (-) buttons to adjust the displayed password numbers.
3. Click the “Start/Pause” button to accept each entered number and move to the next digit.
4. If the password is incorrect, (default manufacture password is: 0000) the ‘Wrong Password’ screen appears for 3 seconds.
5. On entering the correct password, the user will be able to access the Advanced Mode.

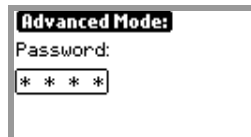


Figure 20: Advanced Mode Password screen

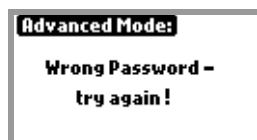


Figure 21: Wrong Password screen

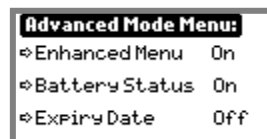
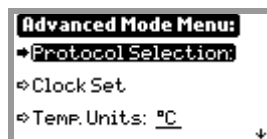


Figure 22: Advanced Mode Menu screens

Protocols Selection

The program library contains a list of predefined protocols. After entering the correct password, the physician will be able to select treatments from this library. The patient will have access to the selected treatments only. An abbreviated protocol name will be displayed in the ‘Protocols Library’ screen.



Figure 23: Program Library screen

1. Click the “Start/Pause” button to enable the selected protocol. An ‘X’ appears in the checkbox.
2. Scroll down using the (↓) button for viewing additional protocols.
3. Press (+) for additional information regarding the highlighted protocol (examples of protocol information are given below).
4. Press (-) to exit.

Example of pre-loaded protocols:

Protocol 2 Summary:

Name: IFC 5kHz/50Hz/H

Waveform: IFC (Premodulated)

High frequency current, where the amplitude is modulated with a low frequency sine wave.

Treatment Time [min]

Treatment Time = 30 min

Temperature parameters:

Temperature mode: Constant

Temperature = 40°C

Waveform parameters:

Carrier Frequency = 5000 Hz

Beat Frequency = 50 Hz

Output Mode = Constant Voltage

Amplitude = 60 V

Duty Cycle = 33 %

Setting the Clock:

In the Advanced Mode:

1. Press the (↓) button to scroll down to 'Clock Set'.
2. Press the **"Start/Pause" button** to enter the Clock Set screen.
3. To set the time and date, the Time and Date entry fields will blink until they are selected.
4. Scroll between the clock parameters using the (↓) button.
5. Use the (-) and (+) buttons to select the desired Time/Date.
6. Press the **"Start/Pause" button** to accept the new setting.

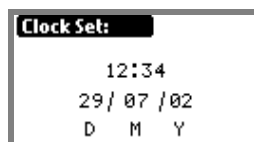


Figure 24: Clock Set screen

Setting the Temperature Units

The ELFcare™ device enables the user to work in Fahrenheit or Celsius, according to his convenience. Switching between the two scales is simple and the steps are described below.

In the Advanced Mode:

1. Press the (↓) button to scroll down to 'Temp. Units'.

Toggle between Fahrenheit ("F") and Celsius ("C") using the **"Start/Pause" button**

Display Feature Selection

In the Advanced Mode:

1. Press the (↓) button until the Enhanced Menu is highlighted
2. Push the **"Start/Pause"** button and choose Enhanced Menu option **"On"** or **"Off"**

Option switching-off «Enhanced Menu» will cancel treatment categories and will cancel screen "Category"

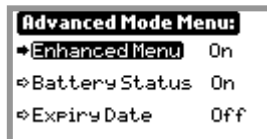
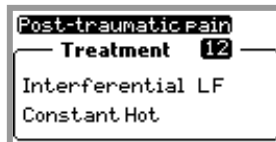


Figure 25: Enhanced Menu screen



Enhanced Menu **"On"**



Enhanced Menu **"Off"**

Figure 26: Treatment selection screen according to Enhanced Menu state

3. Press the (↓) button until the "Battery status" is highlighted (Figure 27).
4. Push the **"Start/Pause"** button and choose "Battery status" display option **"On"** or **"Off"**

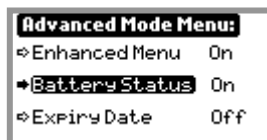


Figure 27: Battery Status screen

Setting the Expiry Date

1. Press the (↓) button until the "Expiry Date" is highlighted.



2. Press the **"Start/Pause"** button to enter the Expiry Date screen.
3. Press **"Start/Pause"** button for Limit Enable
4. Press the (↓) button until the "Date" is highlighted (Figure 28).
5. Date entry fields will blink until they are selected.
6. Use the (-) and (+) buttons to select the desired Date.

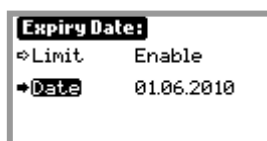


Figure 28: Expiry Data Limit Enable screen

7. Press the **"Start/Pause"** button to accept the new setting.

Change Password

1. Press the (↓) button until the “Change Password” is highlighted.



Figure 29: Change Password screen

2. Press the “**Start/Pause**” button to enter the “New password” screen.
3. Click the (+) or (-) buttons to adjust the displayed new password numbers (for example 1234).



Figure 30: New Password screens “New password”

4. Click the “**Start/Pause**” button to accept each entered number and move to the next digit.
5. On entering the new password, the user will enter to the “Confirm Password” screen.
6. Enter the password once again, if the password is correct, the ‘Password accepted’ screen appears for 3 seconds, if isn't - ‘Password not accepted’

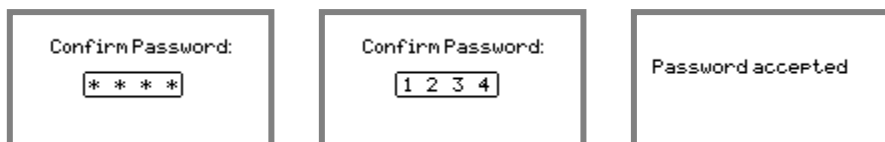


Figure 31: New Password screens “Confirm Password”

System Help



Figure 32: Help screen

1. While in the 'Main Menu' scroll down and press the **"Start/Pause"** button to activate the Help function (see **שגיאה! מקור ההפניה לא נמצא.**).
2. Press the 'About' function for product ID, licensing and other information.
3. Press the Topics function to see what topics are available.
4. Press (-) to exit.

Help About

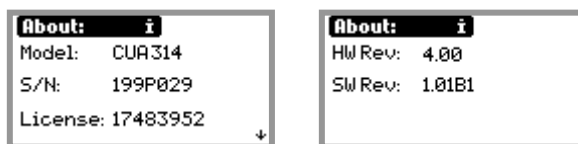


Figure 33: About screens

1. In the Help menu, press **"Start/Pause"** to activate the 'About' function.
2. Press the (↓) button to read the information provided.
3. Press (-) to exit.

Help Topics

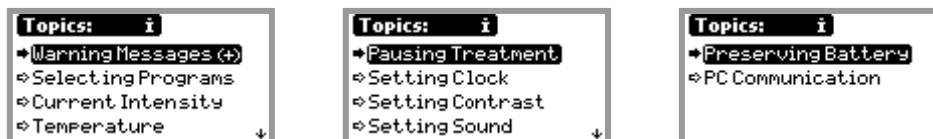


Figure 34: Topics screens

1. In the Help menu, press **"Start/Pause"** to activate the 'Topics' function.
2. Press the (↓) button to see what topics are available.
3. Press (-) to exit.

COMMUNICATION WITH PC (OPTIONAL)

The **ELFcare™** control unit works in conjunction with a fully integrated software package called **ELFsoft™**. The device supports USB communication interface.

USB Communication



Figure 35: USB Communication screen

1. Insert the PC Outlet Connector from the computer into the USB connector (8) on the **ELFcare™** Control Unit.
2. Turn the unit on and the 'Communication' screen will automatically appear.

Unit Problem

The unit performs self-testing during operation, and if a malfunction occurs the 'Unit Problem' message will be displayed. The treatment will immediately be terminated. For additional information, see the Troubleshooting Guide below.

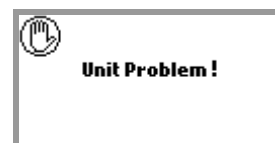


Figure 36: Unit Problem screen

Troubleshooting Guide

In case of difficulty, please check the following Troubleshooting Guide before seeking service.

| Problem | Solution |
|---|--|
| Problem with Control Unit functionality | ❖ Press the "On/off" button and hold for 7-8 seconds |
| The 'Unit Problem' message appears | ❖ Shut down the ELFcare™ and restart. ❖ Press the "On/off" button and hold for 7-8 seconds |
| There is no sound or the sound is too loud | ❖ Adjust the Sound Volume. |
| The display cannot be seen properly | ❖ Adjust the Display Contrast. |
| The temperature is set in °F and not in °C (or visa versa) | ❖ Go to Temp. Units in the Advanced Mode menu and change the units accordingly |
| The unit switched off automatically | ❖ Restart the ELFcare™ device. ❖ Note that the device automatically switches off after 3 minutes if untouched, unless the system is operating in treatment mode. |
| The Thermal surface (14) temperature or electrical intensity is too high / low | ❖ Press the (+) or (-) buttons to either increase or decrease the respective values. |
| The desired program number does not appear in the 'Main Menu' screen | ❖ Ensure that the desired program was enabled in the Advanced Mode 'Program Library'. |
| The buttons are not functioning | ❖ Press the "On/off" switch for at least 7-8 seconds. This will reset the system. |

All repairs and maintenance, including replacement of batteries, should be carried out by authorised personnel only (qualified service).

Qualified service is defined as service qualified by the manufacturer.

Information regarding equipment parts designated as repairable by the manufacturer, such as instructions or reference information regarding such repairs, will be provided on request.

Fuses and other interchangeable or detachable parts should be replaced only with parts provided by the manufacturer.

All disposable parts should be disposed of appropriately (e.g. batteries etc.)

MAINTENANCE AND CARE

To clean, turn the unit “off” and unplug the power supply.

- The **ELFcare™** case, lead wires and the electrode may be cleaned by wiping with a damp cloth or mild cleaning solution. Avoid abrasive cleaners.
- Do not immerse the Control Unit, Split Unit, lead wires, ThermoElectrode and do not spray directly on them. It is best to moisten a cloth, and then wipe the surface.

LABELING INFORMATION

Typical Marking:

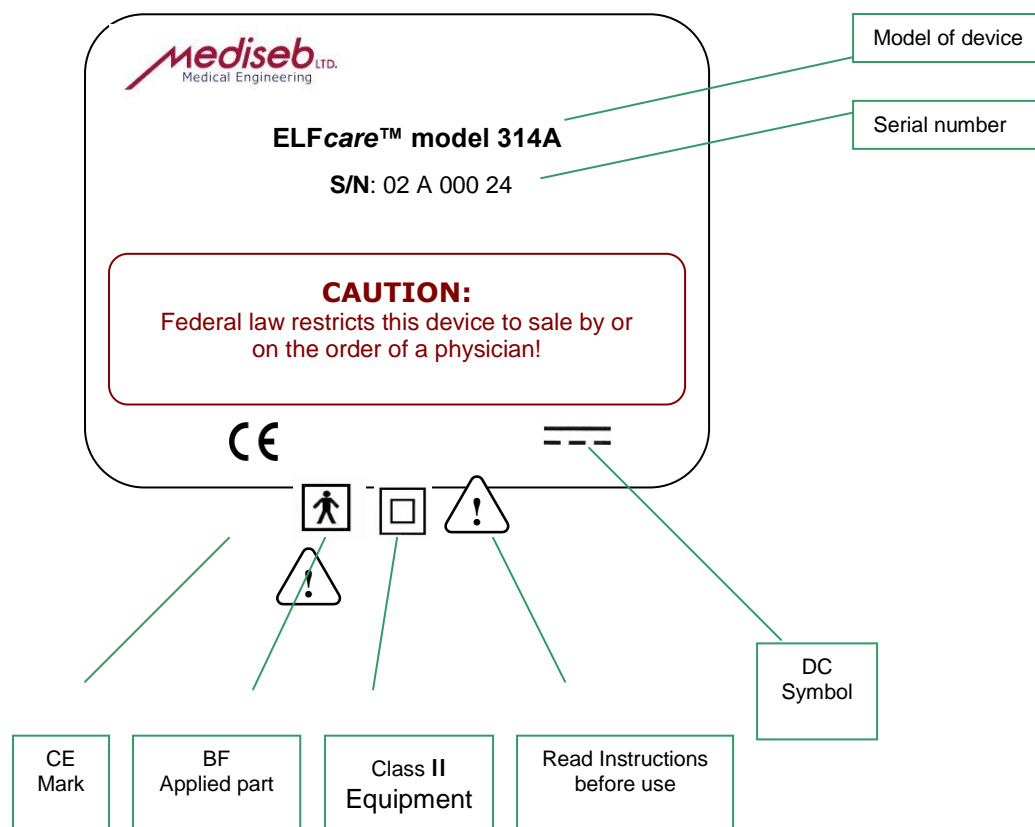


Figure 37: Control Unit Label

ORDERING INFORMATION:

Use the following description when ordering the **ELFcare™** model:

| Model Feature | ELFcare™ 314A | ELFcare™ 314B | ELFcare™ 314C | ELFcare™ 314D | ELFcare™ 314E | ELFcare™ 314F | ELFcare™ 314G |
|--|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|
| Electrode Type: | | | | | | | |
| ThermoElectrode | ● | ● | ● | | | | |
| Thermal (Hot/Cold) | | | | ● | ● | | |
| Ordinary electrodes | ● | ● | ● | | | ● | ● |
| Electrotherapy Waveforms: | | | | | | | |
| IFC (Premodulated Interferential) | ● | ● | ● | | | ● | ● |
| Russian Current | ● | ● | ● | | | ● | ● |
| VMS Burst | ● | ● | ● | | | ● | ● |
| Symmetric Biphasic Rectangular Pulses | ● | ● | ● | | | ● | ● |
| Asymmetric Biphasic Pulse ¹ | ● | ● | ● | | | ● | ● |
| Monophasic Pulses ¹ | ● | ● | ● | | | ● | ● |
| Interrupted Direct Current ¹ | ● | ● | ● | | | ● | ● |
| Diadynamic Current ¹ | ● | ● | ● | | | ● | ● |
| Microcurrent | ● | ● | ● | | | ● | ● |
| Preset Protocols capacity: | | | | | | | |
| 10 Protocols | | | ● | | | | ● |
| 25 Protocols | | ● | | | ● | ● | |
| 99 Protocols | ● | | | ● | | | |
| Communication: | | | | | | | |
| Download protocols and system updates | ● | ● | ● | ● | ● | ● | ● |
| Physiotherapy Software modules (on PC): | | | | | | | |
| Physiotherapy Guide (SPG) | ● | ● | ● | | | | |
| Treatment Waveform Builder (STWB) | ● | ● | ● | | | | |

¹ Not installed for U.S. market

| Standard accessories: | |
|-----------------------|--|
| CUA-314 | Control Unit for <i>ELFcare™</i> 314A model |
| CUB-314 | Control Unit for <i>ELFcare™</i> 314B model |
| CUC-314 | Control Unit for <i>ELFcare™</i> 314C model |
| CUD-314 | Control Unit for <i>ELFcare™</i> 314D model |
| CUE-314 | Control Unit for <i>ELFcare™</i> 314E model |
| CUF-314 | Control Unit for <i>ELFcare™</i> 314F model |
| CUG-314 | Control Unit for <i>ELFcare™</i> 314G model |
| ETE-314 | ThermoElectrode, supplied with <i>ELFcare™</i> 314A,B,C models |
| TE-314 | Thermal Unit, supplied with <i>ELFcare™</i> 314D,E models |
| BS1-314 | Belt Strap, size 60 cm |
| BS2-314 | Belt Strap, size 100 cm |
| ADEL-314 | Lead Wire for Ordinary Electrodes |
| CB-314 | Carrying Bag |
| PS-314 | Medical grade Power Supply, Input: 100-240 VAC, Output: 6.5VDC ±5%, 3A |
| UM-314 | User Manual for <i>ELFcare™</i> models 314A-314G |
| Optional accessories: | |
| BS3-314 | Belt Strap, size 150 cm |

* For models 314F and 314G, Mediseb recommends use of electrodes manufactured in the United States by Axelgaard Manufacturing Company. Two sizes are available, 2" by 2" and 2" by 3.5".

ORDERING SAMPLE:

ELFcare™ - 314A

| Model |
|------------------------|
| 314A, 314B, 314C, 314D |
| 314E, 314F, 314G |

The above package will come with the following items:

- CUA-314 Control Unit for *ELFcare™* 314A model
- ETE-314 ThermoElectrode
- BS1-314 Belt Strap size: 60 cm
- BS5-314 Belt Strap size: 100 cm
- UM-314 User Manual
- PS-314 Power Supply
- CB-314 Carrying Bag

Note: Items 5-7 are standard parts for all orders

SPECIFICATIONS

TECHNICAL DATA

Electrical Stimulation:

| | |
|-------------------|---|
| Waveforms: | IFC(Premodulated Interferential), Russian Current, VMS Burst, Symmetric Biphasic Rectangular Pulses, Microcurrent, Asymmetric Biphasic Pulse ¹ , Monophasic Rectangular Pulses ¹ , Monophasic Triangular Pulses ¹ , Interrupted Direct Current ¹ , Diadynamic Current ¹ (DF,MF,CP,LP) |
| Mode: | Constant Voltage / Constant Current |
| Current Amplitude | 0-50mA at 500Ω |
| Voltage Amplitude | ±60V Peak at 10 kΩ |
| Pulse Width: | 20μS-1000mS |
| Pulse Rate: | 1Hz-10KHz |

Temperature Stimulation:

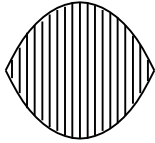

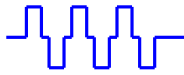

| | |
|-------|--------------------------------------|
| Range | 12°C - 42°C / 53°F - 108°F (on skin) |
|-------|--------------------------------------|

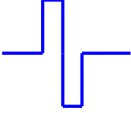
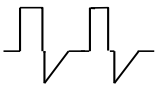


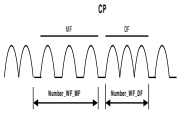
General:

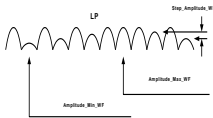
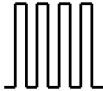



| | |
|--|--|
| Display | <u>Graphic OLED or LCD (STN) 128 x 64 dots</u> |
| User guidance | On screen |
| Programming capabilities: | Up to 99 protocols |
| Communication | <u>USB</u> |
| Treatment time | <u>10-60 minutes</u> |
| Operating temperature | 10°C - 40°C / 50°F - 104°F |
| External Power Supply | Input: 100-240V~, 50-60Hz, 550mA Output: 6.5VDC ±5%, 3A |
| Transportation and storage temperature | 0°C - 50°C / 32°F - 122°F |
| <u>ThermoElectrode build in Electrodes Pair Area</u> | <u>1.57 cm²</u> |
| Control Unit: | |
| Dimensions (L x W x H) | 157 x 91 x 54 mm / 6.2" x 3.6" x 2.1" |
| Weight | 366 gr. / 11.7 ounces |
| ThermoElectrode Weight | 208 gr. / 6.7 ounces |
| Battery | Internal: NiMH Battery pack 4.8V/2200 mAH |

Not installed for U.S. market

DETAILED AVAILABLE WAVEFORMS:

| No. | Type Name: | Waveform: | Technical Characteristic: | |
|-----|--|---|---------------------------|--|
| | | | Description | |
| 1. | IFC (Premodulated Interferential) |  | Description | High frequency current, amplitude modulated with low frequency sine |
| | | | Carrier Frequency | 2kHz (*) / 5kHz/10kHz(*) |
| | | | Beat Frequency | 1-200 Hz |
| | | | Current, Amplitude | 0-50 mA into 500 ohm |
| | | | Voltage (max) | ±60V Peak |
| | | | Waveform Duty Cycle | 33% max |
| | | | Sweep Time | 15 sec |
| | | | Sweep Frequency | 1-200 Hz |
| | | | Cycle Time | User defined or continuous |
| | | | Ramp Up/Down | 0-10 sec |
| 2. | Russian Current |  | Description | Sine wave current |
| | | | Carrier Frequency | 2500 Hz |
| | | | Burst Frequency | 20-100 Hz |
| | | | Current, Amplitude | 0-50 mA into 500 ohm |
| | | | Voltage (max); | ±60V Peak |
| | | | Duty Cycle | 10-33% |
| | | | Cycle Time | User defined or continuous |
| | | | Ramp Up/Down | 0-10 sec |
| 3. | VMS Burst |  | Description | Alternate current with positive and negative rectangular pulses and interphase intervals |
| | | | Burst Frequency: | 1-200 bps |
| | | | Phase duration: | 20-300 µsec |
| | | | Interphase Interval: | 100 µsec |
| | | | Current, Amplitude | 0-50 mA into 500 ohm |
| | | | Voltage (max) | ±60V Peak |
| | | | Waveform Duty Cycle | 20% max |
| | | | Cycle Time | User defined or continuous |
| | | | Ramp Up/Down | 0-10 sec |
| 4. | Microcurrent |  | Description | A direct or alternate current with a rectangular pulse and low amplitude |
| | | | Beat Frequency | 0.1-1000 Hz |
| | | | Current, Amplitude | 10-1000 µA into 500 ohm |
| | | | Ramp Up/Down | 1 sec (+/- only) |
| | | | Alternating Time | 2.5 sec |
| | | | Polarity | (+), (-), (+/-) |

| No. | Type Name: | | Waveform: | Technical Characteristic: | |
|-----|---|-------------------|---|--|--|
| | | | | Description | |
| 5. | Symmetric Biphasic Rectangular pulse | |  | Alternate current with positive and negative rectangular pulses | |
| | | | | Pulse Frequency | 1-200 Hz |
| | | | | Phase duration | 50-300 µsec |
| | | | | Current, Amplitude | 0-50 mA into 500 ohm |
| | | | | Voltage, max | ±60V Peak |
| | | | | Waveform Duty Cycle | 20% max |
| | | | | Output Mode | Normal, Modulation, Burst |
| | | | | Frequency Modulation | 1.25-10KHz |
| 6. | (*) Asymmetric Biphasic Pulse | |  | Alternate current with positive rectangular and negative triangular pulses | |
| | | | | Pulse Frequency | 1-300 Hz |
| | | | | Phase duration | Positive:(0.2-100)msec; Negative: (0.4-200)msec; negative duration/positive duration = 2 |
| | | | | Current, Amplitude | 0-50 mA into 500 ohm |
| | | | | Voltage, max | ±60V Peak |
| | | | | Waveform Duty Cycle | 20% max |
| | | | | Ramp Up/Down | 0-10 sec |
| | | | | Output Mode | Normal, Modulation, Burst |
| 7. | (*) Diadynamic | MF Current |  | Description | 5-100 Hz Half-wave rectified current |
| | | | | Current, Amplitude | 0-50 mA into 500 ohm |
| | | | | Voltage, max | 60 V |
| | | | | Waveform Duty Cycle | 33% max |
| | | DF Current |  | Description | 10-200 Hz full-wave rectified current |
| | | | | Current, Amplitude | 0-50 mA into 500 ohm |
| | | | | Voltage, max | 60 V |
| | | | | Waveform Duty Cycle, max | 33% |
| | | CP Current |  | Description | MF and DF current. Alternates the MF and DF every few seconds |
| | | | | Current, Amplitude | 0-50 mA into 500 ohm |
| | | | | Voltage, max | 60 V |
| | | | | Waveform Duty Cycle | 33% max |

| | | | | | |
|-----|--|-------------------|---|---------------------|--|
| | | LP Current |  | Description: | LP alters the amplitude of every other DF pulse |
| | | | | Current, Amplitude | 0-50 mA into 500 ohm |
| | | | | Voltage, max | 60 V |
| | | | | Duty Cycle | 33% max |
| | | | | Ramp Up/Down | 0-10sec |
| 8. | (*) Monophasic Rectangular Pulsed | |  | Description | A direct current with a rectangular pulse |
| | | | | Pulse Duration | Pulse: 0.02-250msec |
| | | | | Pulse Frequency | 1-10,000 Hz |
| | | | | Current, Amplitude | 0-50 mA into 500 ohm |
| | | | | Voltage, max | 60 V |
| | | | | Duty Cycle | 20% max |
| | | | | Cycle Time | User defined or continuous |
| | | | | Ramp Up/Down | 0-10 sec |
| | Trabert 2-5 (Ultra-Reiz) | |  | Description | A direct current with a rectangular pulse having a phase duration of 2 ms and a phase interval of 5 ms |
| | | | | Phase duration | 2 msec |
| | | | | Phase interval | 5 msec |
| | | | | Duty Cycle | 20% max |
| | | | | Current, Amplitude | 0-50 mA into 500 ohm |
| | | | | Voltage, max | 60 V |
| | | | | Ramp Up/Down | 0-10 sec |
| 9. | (*) Monophasic Triangular Pulsed | |  | Description | A direct current with a triangular pulse |
| | | | | Pulse Duration | 1-250msec |
| | | | | Pulse Frequency | 1-300 Hz |
| | | | | Duty Cycle | 30% max |
| | | | | Current, Amplitude | 0-50 mA into 500 ohm |
| | | | | Voltage, max | 60 V |
| | | | | Ramp Up/Down | 0-10 sec |
| 10. | (*) Interrupted direct current | |  | Description | A direct current with a short-time interrupts |
| | | | | Pulse Frequency | 8000 Hz |
| | | | | Duty Cycle in Pulse | 95% |
| | | | | Current, Amplitude | 0-50 mA into 500 ohm |
| | | | | Voltage, max | 60 V |
| | | | | Waveform Duty Cycle | 20% max |

1. For U.S. market, the asterisk (*) marked currents are not installed

LIMITED WARRANTY

Mediseb Ltd. ("the company") warrants that the **ELFcare™** system ("the product") is free of defects in material and workmanship. This limited warranty shall remain in effect for one (1) year from the date of the original consumer purchase of this product and extends to any owner of the product during the warranty period. Accessories included as standard with the product (as listed in the users manual) are warranted for 90 days. If this product fails to function during the warranty period because of defects in the materials or workmanship, the company or the selling dealer will replace or repair this product without charge within a period of 30 days from the date on which the defective product is returned to the company or to the dealer. The company or the dealer will ship the replacement or the repaired product to the consumer's facility. All repairs must be performed by a service center authorized by **Mediseb Ltd.** Any modifications or repairs performed by unauthorized centers or groups will void this warranty. To participate in warranty coverage, this product's warranty registration card (included with the product) must be filled out and returned to **Mediseb Ltd.** by the original owner within ten business days of purchase.

This Warranty does not cover:

2. Replacement parts or labor furnished by anyone other than the company, the dealer or an approved company service agent.
3. Defects or damage caused by labor furnished by someone other than the company, the dealer or an approved company service agent.
4. Any malfunction or failure of the product while it is in the possession of the owner during the warranty period if the malfunction or failure is not caused by a defect in material or workmanship, or if the malfunction or failure is caused by unreasonable use, including the failure to provide reasonable and necessary maintenance.

The company shall not be liable for incidental or consequential damages to property or business.

Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation or exclusion may not apply to you.

To obtain service from the company or the selling dealer under this warranty, the owner must do or abide by the following:

1. A written claim must be made within the warranty period to the company or the selling dealer. If the claim is made to the company, written claims may be sent to:
Mediseb Ltd. P.O.B 12678, Herzliya, 46733, Israel
Tel.: +972-9-950 0885, Fax. +972-9-950 0886
E-mail: info@mediseb.com

2. The product must be returned to the company or the selling dealer by the owner.

This warranty gives you specific legal rights. You may also have other rights, which vary from state to state.

The company does not authorize any person or representative to create for it any other obligation or liability in connection with the sale of the product. Any representation or agreement not contained in the warranty shall be void and of no effect.



6 Galgaley Ha'plada St.,
P.O.B. 12678, Herzlia ISRAEL
Tel: (+972) 9-950 0885
Fax: (+972) 9-950 0886
E-mail: info@mediseb.com
[http:// www.mediseb.com](http://www.mediseb.com)